

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BIOGEN INC., BIOGEN SWISS	)
MANUFACTURING GMBH, and	)
ALKERMES PHARMA IRELAND	)
LIMITED,	)
	)
Plaintiffs,	)
	)
v.	) C.A. No. 23-732 (GBW)
	)
ZYDUS WORLDWIDE DMCC, ZYDUS	)
PHARMACEUTICALS (USA) INC., and	)
ZYDUS LIFESCIENCES LIMITED,	)
	)
Defendants.	)

**STIPULATION AND [PROPOSED] ORDER REGARDING INFRINGEMENT**

Plaintiffs Biogen Inc. and Biogen Swiss Manufacturing GmbH, and Alkermes Pharma Ireland Limited (collectively, “Plaintiffs”), and Defendants Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (collectively, “Zydus”), stipulate and agree as follows:

WHEREAS, Zydus has filed Abbreviated New Drug Application (“ANDA”) No. 218596 with the United States Food and Drug Administration seeking approval for its proposed generic version of VUMERITY® (diroximel fumarate) delayed-release capsules for oral use, 231 mg (“Zydus’s Proposed ANDA Product”);

WHEREAS, Plaintiffs have sued Zydus for infringement of U.S. Patent Nos. 8,669,281 (“the ’281 Patent”), 9,090,558 (“the ’558 Patent”), and 10,080,733 (“the ’733 Patent”) (“Asserted Patents”);

WHEREAS, Zydus has asserted various defenses in response to Plaintiffs’ Complaint;

WHEREAS, the parties wish to narrow the issues in dispute and have reached agreement on the issues set forth below;

NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED by the parties as follows:

1. Zydus stipulates and agrees that the submission of its ANDA No. 218596 has infringed under 35 U.S.C. § 271(e)(2)(A), and the making, using, offering to sell, selling, or importing of Zydus's Proposed ANDA Product will infringe, induce infringement, and/or contribute to infringement of, Claims 1-4 of the '281 patent, Claims 1-2 of the '558 Patent, and Claims 1-4 of the '733 Patent, unless, as to each claim, the claim is found to be invalid and/or unenforceable.

2. Plaintiffs and Zydus hereby agree not to seek written or deposition discovery on issues related solely to infringement/non-infringement; the parties are entitled to seek discovery on any other relevant issue that is not stipulated to, including remedies.

3. Zydus agrees to limit depositions of Plaintiffs' witnesses to two Rule 30(b)(1) inventor depositions and Rule 30(b)(6) depositions on issues that have not been stipulated to (along with Rule 30(b)(1) notices to those designees), including remedies, provided that Plaintiffs agree that any inventor or corporate representative not presented for deposition will not appear at trial (and to the extent Plaintiffs intend to call a witness at trial that has not been deposed, they will make available any such witness for deposition prior to trial).

4. Plaintiffs agree to limit depositions of Zydus's witnesses to Rule 30(b)(6) depositions on issues that have not been stipulated to (along with Rule 30(b)(1) notices to those designees), including remedies, provided that any witness or corporate representative not presented for deposition will not appear at trial (and to the extent Zydus intends to call a witness at trial that has not been deposed, it will make available any such witness for deposition prior to trial).

5. Either party may seek to depose additional witnesses by agreement of the party whose witness is to be deposed, or by good cause shown, i.e., by order of the Court.

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July 31, 2024

SO ORDERED, this \_\_\_\_\_ day of \_\_\_\_\_, 2024.

THE HONORABLE GREGORY B. WILLIAMS  
UNITED STATES DISTRICT JUDGE  
DISTRICT OF DELAWARE